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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,169	04/19/2001	Theresa Ann Jeary	P24,622 USA	3922

61214 7590 05/18/2007
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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/744,169

Applicant(s)

JEARY ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,20,23-34,36-40,45-51 and 55-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,20,23-34,36-40,45-51 and 55-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the decision from pre-appeal brief review dated 03/01/07,
PROSECUTION IS HEREBY REOPENED. New ground of rejection is set forth below.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4, 5, 20, 25-27, 31-33, 36-40, 47-51 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al. US 5,958,458, in view of Van Balken et al. US 6,183,780.

Norling teaches a pharmaceutical multiparticulate formulation in the form of coated cores (abstract). The core is in the form of pellets, comprising active agent and excipient (columns 2, lines 33-42; and column 13, lines 29-67). The active agent includes antidepressants (column 6, lines 35-40). The coated multiparticulate is formulated into oral solid dosage form including tablet, capsule, powder or granule suitable to release active agent during a 24 hours period (column 13, lines 20-36). Suitable coating polymers includes ethyl cellulose, Eudragit[®] E, Eudragit[®] RS or RL, polyvinyl acetate phthalate (columns 9-10).

It is noted that the Norling does not expressly teach the release profiles. However, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Accordingly, it is the position of the examiner that the

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release profile is inherent because Norling teaches the use of the same rate control release polymer, e.g., Eudragit® E, Eudragit® RS or RL.

Norling does not explicitly teach fluvoxamine in the composition.

Van Balken teaches an oral delayed immediate release formulation comprising active core coated with rate control release polymer (columns 5-6). The active agent in the core is an antidepressant, e.g., fluvoxamine (column 5, lines 24-25). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify pharmaceutical multi-particulate formulation of Norling using fluvoxamine as an antidepressant in view of the teaching of Van Balken, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

Claims 1, 2, 4, 5, 20, 23-34, 36-40, 45-51 and 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al. US 5,958,458, in view of Van Balken et al. US 6,183,780 and Curatolo et al. WO 99/01122.

It is noted that the Norling does not expressly teach the release profiles as well as the blood serum level.

Curatolo teaches a delayed release formulation for SSRI compound, the composition comprising an active core, and a delayed release coating comprising the claimed ammonio methacrylate copolymer and plasticizer (abstract; and page 12, lines 1-21). Curatolo further teaches the amount of coating gain on the core is from 3-70%.

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Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the amount of the coating with the expectation of at least similar results to the claimed invention. This is because Curatolo teaches the use of the same coating polymer in the same amount, and for the same purpose, namely, a delayed release dosage form suitable to delivery SSRI compound in a safe and effective way, such as decrease in the incident of severity of nausea, diarrhea, and regurgitate (page 33, lines 16-20).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to be 'S. Tran', written over a horizontal line.

S. Tran
Examiner
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